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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,264	06/22/2001	Sean H. Adams	11669.187USU1	8727

23552 7590 10/27/2005

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/888,264	Applicant(s) ADAMS ET AL.	
	Examiner Jon Eric Angell	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,28,34-38,41,43,46,52,53 and 74-78*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Anne-Marie Falk

Jon Eric Angell

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: Applicants have amended claims 1 and 41 such that all pending claims are now drawn to a method of screening for compounds that effect mitochondrial uncoupling comprising contacting a mammalian cell or tissue sample with a candidate compound and analyzing an isolated contacted mammalian cell or tissue sample for expression of a polypeptide encoded by SEQ ID NO: 2 or which is 95% identical to the polypeptide encoded by SEQ ID NO: 2 and which has mitochondrial uncoupling activity. It is noted that previous previous Office Actions have indicated that the claimed methods were enabled for contacting a mammalian cell or tissue sample in vitro and performing the analysis in vitro (e.g, see Office Action mailed on 7/26/2005). Applicants have amended the claims such that the analysis steps are performed in vitro, however, the claims still encompass steps wherein the candidate compound is administered to a cell in vivo (i.e., in a subject), which was previously indicated as being non-enabled. Applicants assert in their response filed 10/5/2005 that they have enabled contacting a cell or tissue sample with a candidate compound both in vitro and in vivo. It is respectfully pointed out that in order to be able to succesfully perform the claimed method, the specification would have to be enabling for administering ANY candidate compound to a subject by any means or route of administration such that when ANY cell of the subject is isolated, it can be used to determine if the candidate compound changes expression of the 2-oxoglutarate carrier protein (OGC) in the isoalted cell. Since it is unpredictable if a compound that actually alters OGC expression (let alone a compund that does not alter OGC expression) would have a effect on a particular target cell when administered by general systemic administration to a subject, the claimed method could not be used to predictably determine if a compound affects mitochondrial uncoupling without performing an undue amount of additional experimentation. Therefore, the instant claims are not enabled for their full scope. It is noted that the claims are enabled for the method wherein all of the steps are performed in vitro. Specifically,the claims are enabled for: A method for screening for compounds that affect mitochondrial uncoupling wherein the method comprises contacting a mammalian cell or tissue sample with a candidate compound in vitro; analyzing expression of an 2-oxoglutarate carrier (OGC) polypeptide in the mammalian cell or tissue sample contacted with the candidate compound wherein said OGC polypeptide is at least 95% identical to the polypeptide encoded by SEQ ID NO:1 or SEQ ID NO:2 and has mitochondrial uncoupling activity; analyzing mitochondrial membrane potential in said mammalian cell or tissue sample contacted with the candidate compound; wherein a change in the expression of the OGC polypeptide and a change in mitochondrial membrane potential relative to a control cell indicates that the candidate compound affects mitochondrial uncoupling. It is noted that amending the claims as such would obviate the rejections and the claims would be allowable.